

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference FR3531WO	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/EP2004/000487	International filing date (day/month/year) 22.01.2004	Priority date (day/month/year) 27.03.2003
International Patent Classification (IPC) or national classification and IPC		
Applicant FRESENIUS KABI DEUTSCHLAND GMBH		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of **5** sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-9 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. 1-10 _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☒ the drawings:
- sheets 1/5-5/5 _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	1-10	YES
	Claims		NO
Inventive step (IS)	Claims	1-10	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
1. Reference is made to the following documents:			
D1: DE 100 30 474 C (FRESENIUS KABI DE GMBH)			
21 February 2002 (2002-02-21)			
D2: US-A-3 913 882 (MOULET CAMILLE)			
21 October 1975 (1975-10-21).			
2. Document D1 is considered to be the prior art closest to the subject matter of claim 1. Said document discloses (the references in parentheses are to D1):			
a connector for packagings that contain medical fluids, said connector having a connection piece (1) comprising a throughhole (5) for accommodating a spike for the withdrawal of fluid and a sealing part (6) which can be placed on the connection piece and which seals the throughhole (5) in the connection piece. The connection piece (1) is inserted into a connecting element (22) which is welded into an infusion bag, and sealingly connected to said connecting element.			
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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Thus, the subject matter of claim 1 differs from the known connector in that the connection piece comprises an elastically deformable clamping element configured as a tubular section with a cross-section that does not remain constantly circular and in that said clamping element merges into a base part which broadens out on both sides and can be incorporated into the packaging.

Thus, the subject matter of claim 1 is novel (PCT Article 33(2)).

The problem addressed by the present invention can therefore be considered to be that of simplifying the manufacture of the bag.

The solution to the above problem, as proposed in claim 1 of the present application, involves an inventive step (PCT Article 33(3)). The reasons are as follows (PCT Article 33(3)):

D1 contains nothing to suggest designing the connection piece of the connector in the form of an elastically deformable clamping part since said document concerns only a rigid connection piece intended for insertion into a piece of tubing connected to the infusion bag.

D2 relates only to a hose clamp for a flexible pipe with a cross-section that does not remain

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

constantly circular and no connector and, in consequence, said document likewise does not contain anything to suggest providing a connector with an elastically deformable clamping element.

After the bag has been filled, the connection piece, which can be incorporated directly into the packaging, can be clamped with a suitable clamping device in such a way that, when the sealing part is placed on the connection piece, there is no risk of fluid escaping from the bag.

Claims 2 to 9 are dependent on claim 1 and, thus, likewise satisfy the requirements of the PCT in respect of novelty and inventive step.